

Tape # 11

Dr. M.E. DeBakey

Houston, Texas

8/11/72

Notes on Cooley Investigation

Side.A

DR. DeBAKEY: I think that what is more important to me is that they have no complexes. They're pretty well-rounded out individuals with their feet planted firmly on the ground. And they know what they want to do now. They've got their goals and they're working on them and they're.. fortunately those that are married--the three that are married are married to three fine girls. And they're pretty substantial citizens. So whatever I did really didn't harm them. Whatever Diana did, she did right. So I don't really feel guilty about that at all.

SCHANKE: Did you have periods when you did? There must have been some?

DR. DeBAKEY: Yes, I used to be a little..used to get a little guilty about it and feel a little frustrated because I wanted

DR. DeBAKEY: to do what I wanted to do, and yet I felt I had to be with them. And this was especially during the holidays and at Christmas and things like that. And I'd feel guilty leaving the family to come and do some work or something of that sort. But, Diana had a great sense of humor, you know. And she used to, in a humorous way, would pass things off. So that there wasn't. . We never had any great problems that we fought over or anything like that.

SCHANKE: You weren't fighters. When would you fight?

DR. DeBAKEY: Oh, well, we had disagreements. Sometimes, you know, she'd get mad at me. But, not long.

SCHANKE: Well, did she at some point early in your marriage go through the standard crisis of the doctor's wife? All women who are married to doctors say something like that.

DR. DeBAKEY: No, fortunately, no. I think it's her personality more than anything else. Her adjustment was because of her personality. And she loved the children and she loved to do things for them. You know, in the early days she

DR. DeBAKEY: was what they call the den mothers and that sort of thing. You know, she used to take care of a lot of kids. She'd have them over to the house and she'd take them to clubs and things of that sort. And she adjusted.. Well, not only that, but Diana basically had a lot of pride in what I was doing. And while she didn't go around bragging, I know just from the way she acted and what she'd say to other people from time to time that would get back to me, that she took great pride in what I was doing. And so that was her basic, you might say, means of compensating. And she kept..then too, she kept an interest in the patients. Took a lot of pride in the fact that I had these patients. And she would come and talk to them--foreign patients mainly.

SCHANKE: Did she begin that here? She did, didn't she?

DR. DeBAKEY: Yeah. Yeah.

SCHANKE: She was too busy with little children to get involved in your work before then, wasn't she?

DR. DeBAKEY: That's right. But it came about to some extent from our traveling around the world. She was a good traveler.

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DR. DeBAKEY: She didn't.. She got involved in the way things were there. You know, she never was a typical American traveler. She tried to see what was good wherever she went, even in the most undeveloped places. You know, when we got to India, she'd look for what was good and nice and so on. She would read about the country a bit and learn a little bit about the customs and that sort of thing.

SCHANKE: Did she help you in this respect when you traveled?

DR. DeBAKEY: Oh, yes.

SCHANKE: Sort of instruct you in what was...

DR. DeBAKEY: Oh, yes, she did. She did a lot of reading about it, so she knew a lot about it. She was great on historical background and culture of the country and the people. And she did it as a broad thing, you know. Not as... Not where specifically.. When we went to India, she read a lot about India. She knew a lot about the background and culture and history, but she continued it. You see? And she did the same way.. Well, she lived in France, so she had a kind of a good understanding of French culture

DR. DeBAKEY: and French art and history. And she could speak a little French. And she.. When we got to England, she did the same thing in England. She.. In Scotland and so on. I mean, she was a great traveler--really was. And she was very expressive. She wrote beautiful letters to people. She had a.. I remember when we were away she used to write me about twice a week--in Paris, for example. And she wrote beautifully. I used to encourage her, in fact I encouraged her to try to write a book because she could write so well. But apparently she never did--I don't know. She did...for a while she was working on a little diary--places she went and saw.

SCHANKE: When you were young and first met, was this a sort of incremental romance that gradually grew..?

DR. DeBAKEY: Yeah.

SCHANKE: ..or was it a great dramatic, romantic...?

DR. DeBAKEY: No, it was sort of incremental. Because..

SCHANKE: What do you suppose drew you together?

DR. DeBAKEY: Well, I think we..for a while we were working close together. But she was working mostly in medicine.

DR. DeBAKEY: But we'd go out maybe once a week or there would be other weeks...

SCHANKE: What were you actually doing that made you work together? She was a graduate nurse--a graduate student in nursing.

DR. DeBAKEY: Yeah, but she was doing part-time work at Tulane. And she was on the seventh floor and I was on the eighth floor. And we had patients sometimes and I'd come down and see these patients. And she'd handle..

SCHANKE: She was a nurse at the time?

DR. DeBAKEY: ...arranging it. Yeah. Well, she was sort of a nurse administrator. She really wasn't doing actual nursing. You know, after they get to a certain point, nurses look down on nursing. Yeah, yeah. They're administrators. That's what I call them.

But Diana was not.. She was really built in a sense, her personality was, to nurse. She loved to take care of people and do things for them. And so, even though she was administrative--administrator for that unit, she still would take care of the patients in a way. They weren't sick patients. They were ambulatory. No it was incremental. We didn't have one of these firey

DR. DeBAKEY: romances.

SCHANKE: She must have been quite beautiful then. She was as an older person too, but I mean..

DR. DeBAKEY: Yeah, she was.. Oh, yes. She was very, very attractive. And she was very popular. And, oh, a little later on, I became.. I got a little jealous of her time, you know. And then she recognized this and she obviously liked me. And so, whenever I.. You know, I'd occasionally call and she'd say, "Well, I'm sorry. I've got a date." And I'd get a little upset about it. And I'd say, "A date with whom?" Or something like that. And finally she quit going out with anybody else. So that she was available when I wanted her. But, no we didn't have one of these firey romances and courtships. For one thing, it was broken up, you know, by the fact that we went our different ways. Yeah, but I was so strongly attached to her that I would come to Paris and kept up correspondence with her. And we'd always have a very nice time when we were together. She always...

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SCHANCHE: Was she very fun loving, lively..?

DR. DeBAKEY: Yes. Yeah, she was always happy. She was never..

SCHANCHE: But you were probably intense, serious..

DR. DeBAKEY: Yeah, that's right. But she was very out-going, very happy and felt pleasure in things. Sometime s we'd just walk down the Boulevard walking together, you know. We'd go to the gardens and tour it. But..

SCHANCHE: Did she ever chide you for being too serious?

DR. DeBAKEY: Yeah. Oh, yes.

SCHANCHE: What would she say?

DR. DeBAKEY: Oh, well, she'd say, you know...

SCHANCHE: That you were worrying about Professor Leriche..

DR. DeBAKEY: Yeah. She'd say, "Now listen, you forget about that now. You're with me and I want to have a good time. Don't be thinking about these things." But in a very nice way. Never really upset about it. And.. But we, there's no question about the fact that we became very close. And I never kept anything from her and always shared things with her, even things I was concerned with I'd talk with

DR. DeBAKEY: her about it. She was always very easy to talk with.
And so we had a very, very good life together.

SCHANCHE: You never had great difficult periods?

DR. DeBAKEY: Oh, no, no, no. Because she never carried it long,
you know. And I didn't either. I'm not built that way.
If I get mad, I get mad and it's over with. I can't be
mad long.

SCHANCHE: Did you have poverty periods?

DR. DeBAKEY: No, no, we never did, really. We.. Because we lived..
When we first started together, we had a small apartment.
It was on St. Charles Avenue in a very nice location, but
still very small. And she was never demanding, you know.
She didn't want a lot of luxury things. She didn't like.. She
didn't want me to bring.. give her jewelry, for example.
She was very simple in her tastes. And she didn't need it
either. She.. When she got dressed to go out in the evening
she had a very simple, very often they used to say basic
black dress, and she looked like a knock-out. She didn't
need it.

SCHANCHE: She told me she didn't work after you were married.
She never went back to work.

DR. DeBAKEY: No. She never worked again at all.

SCHANCHE: Well, was something...

DR. DeBAKEY: I didn't want her to work. I told her, I said, "Now, look, I don't want you to work anymore. If you want to do voluntary work that's okay. You're not going to do any more work. I want you to be my.. take care of my house and my home. And if you want to do some voluntary work, well that's okay. " Well, she kept busy. She had a lot of things to do. I didn't want her to work.

SCHANCHE: She told me a story about one of the boys who had meningitis while you were away and she was at home and this seemed to her to have been the, I guess, the most critical --one of the most critical points anyway, in her life.

DR. DeBAKEY: It was, because we were very, very much concerned because the boy..this boy became really sort of..he developed some sort of irrational behavior with it. He was entirely irrational at times. And we were very much concerned.

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DR. DeBAKEY: He dropped out of school. We were really very much worried about him and..

SCHANKE: She seemed to feel a little guilty about it because she had dismissed headaches that he had complained about.

DR. DeBAKEY: Yeah, that's right. We both did. Well, it was so transient. He wasn't critically ill long and .. I'm not too sure really--we never have been absolutely certain and the doctors who examined him hadn't been certain. They all speculated about it being possible. So it could have been just a behavioral pattern that he went through. He never got.. You know, it was never a serious thing, although it was serious to us. You know, he never got in jail and he never committed a crime of any kind. He never stole anything. He never smoked marijuana or took any drugs.

SCHANKE: He dropped out of school and..

DR. DeBAKEY: Yeah, he just decided he was going to drop out of school. And we couldn't figure that out, because he was doing well in school before this happened. And so, fortunately he

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DR. DeBAKEY: got through that period finally and has done extremely well since. His grades at the university are all..He's on the honor list regularly.

SCHANKE: Is he studying archeology?

DR. DeBAKEY: No. No. He's just taking right now just a straight bachelor of arts work. And he graduates this year. But he's now thinking of studying law. Yeah. Which is a big shift in his whole thinking, I think. But, he has sort of become fascinated with law and he's sort of reading a lot about it and became more interested in it now and he talked to me about it and I encouraged him to do it. I think it's great.

SCHANKE: Did you have any great romantic disappointments before you were married to Diana?

DR. DeBAKEY: No. No. I never had any romantic attachments. I went out a great deal. I used to have a good time, but .. One summer for example, I was teaching a course--I was still a student in college--and I taught a course in entomology. It was a graduate course. And I'd never taken the course myself.

SCHANKE: How'd you swing that?

DR. DeBAKEY: Well, the professor of zoology and I. . . The fellow who was supposed to give the course at the last minute got sick and couldn't come down for the course. And there he was. He had nobody to teach this course. And he regarded me, as I guess, one of his bright students. He was the professor of zoology I told you about. And he said, "Now, I want you to do this. Will you do it?" I said, "Well, no, I don't know that I can. I'll do it if I can." He said, "Oh, I know you can." He said, "I'll give you the course background reading and the books and you just skim through it as rapidly as you can and I'll help you with it." And he said, "Here's the outline for it." And so on. Well, it was about two months in the summer--a graduate course at Tulane. And mostly these were school teachers. They were young school teachers that came to take work for their graduate degree and getting credit for it. These were science teachers. And, of course, a lot of them were pretty young. Most of

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DR. DeBAKEY: them..but they were all older than I was. But I mean I was, let's see, I was at that stage in my life I was about twenty. And most of these girls were twenty-two, twenty-four, twenty-five. They were much more experienced than I was. But there must have been about thirty of them in this class. And I'd have to take them on field trips. We'd go out on field trips into the swamps and so on. I remember one time I.. This was on a Sunday and I had to get a collection of snakes for them. So I went out into the swamps south of New Orleans with a gunny sack and these forked sticks we used as kids and picked up a whole variety of snakes. Put them in this gunny sack. Still alive. And I had to rush home. I was staying in a boarding house and I had to rush home to eat because we ate at dinner.

SCHANKE: You told me this story. The snakes started.. You didn't tell me how it came about.

DR. DeBAKEY: Well, that's how it came about, you see. And I had to rush back to get there in time to eat. Because they

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DR. DeBAKEY: had the big meal on Sunday was around noon or one o'clock, something like that. And I just barely made it. And I didn't have time to go to the lab--the laboratory and leave the snakes. So, I put the snakes in the hallway right behind the door as I came in. And then the dining room was right next to the living room, but they opened all together, you see. We were sitting at the dining room table, when we.. The lady that ran the boarding house was sitting at the head of the table and she happened to look there in the hallway--looking through the door that connected with the living room and there was a snake in the middle of the carpet. And boy, she screamed and nearly fell over, you know, and I knew what had happened. So I rushed out there and caught the snake and put him back in the gunny sack. He had squirmed out some little opening in this gunny sack. Then I had a hell of a time apologizing to her. But she was very sweet and she liked me. That's the only reason I stayed.

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DR. DeBAKEY: Because if she'd wanted to throw me out, she really would have thrown me out. And I explained why this had happened and I was sorry. She let me stay.

SCHANKE: Then you had your thirty odd students. Some of whom you were dating.

DR. DeBAKEY: Well, yeah. Sometimes I'd go out with them. Yeah. We had a good time. Sometimes I'd go out with three or four of them.

SCHANKE: Did you learn about women from them?

DR. DeBAKEY: No, I didn't learn about women from any of them. But I mean.. I didn't lead a monastic life. I saw a lot of people and I liked to have a good time. I used to go out regularly. But, I must say that even at that time I was pretty disciplined, because my disciplinary training from earlier days gave me.. developed a real sense of responsibility. So that I wouldn't let my work suffer--my studies. And I had been raised that it was a sin that could befall on me for me to fail anything. It would have been hard for me to live with myself.

SCHANCHE: Worse than all the sins of New Orleans.

DR. DeBAKEY: Oh, yes. And I think, even worse than that, if I didn't really do well too. I mean I had to be at the top of the class or very near it. Or else, I was very unhappy. No, I expected to be there, and I should have been there, you see. I had reached by that time a stage you might say in my life to know that in competition with my fellow man I could compete easily. I didn't have any difficulty in competing with them. And I loved it, you know. Competition--I thrived on it. I wanted to be the top man in the class. And I wanted to be able to have them realize that I was, too. I didn't want to have to tell them. You know. I expected them to know it. So that if I didn't do well.. You know, I remember very.. I remember I was terribly upset and disappointed in a mathematics class in my freshman year at college.

SCHANCHE: You told me that story.

DR. DeBAKEY: You know.

SCHANCHE: Of course there wasn't anyone with ..

DR. DeBAKEY: No. And he was a little astonished that I was concerned about this. He thought I did well. "You did extremely

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DR. DeBAKEY: well. You made the best grade in the class."
I said, "I know, but I only made 80." To me that's
a poor grade.

SCHANCHE: Back to Diana, were there points in your life when she
was absolutely invaluable to you? On foreign trips or
times when she saved you from diplomatic disasters?

DR. DeBAKEY: No, I can't recall any specific incidence of that kind,
Don. You know, to illustrate. The first trip I made
to Russia I had a wonderful experience in the sense
that, I was alone, but I remember so well when I spoke
to some four thousand men in the audience and they
gave me..

SCHANCHE: Standing ovation?

DR. DeBAKEY: ..a standing ovation for it seemed almost interminable even.
It was very warm. But I didn't go to their homes on that
trip. I didn't get close to them. It was all pretty formal.
Now when Diana went with me--the time she went with
me, well, she met their wives and she.. They obviously

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DR. DeBAKEY: took a great liking to her. And she made a good impression on them. And from that point on, we became very close. And we were invited to their homes. So that, she did create, in a sense, an environment which made the relationship far more..

SCHANCHE: Warmer.

DR. DeBAKEY: Yeah, far more amiable and more relaxed and more.. It was a closer kind of relationship and we became on a first name basis, you know. They called her Diana. She was that kind of person.

SCHANCHE: She was closer to every place you went, wasn't she?

DR. DeBAKEY: Yeah, that's right. That's right. So that, in that sense she did add greatly to my relations with these people. But there was no.. I can't recall any crisis that she solved in any way. There really wasn't anything like that.

SCHANCHE: Do you want to go upstairs now?

DR. DeBAKEY: I'm going to have to go in just about five..

SCHANCHE: In about twenty minutes.

DR. DeBAKEY: I think we'd better stop, because I'm going to have to...

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*NOTE: Begin here: "Notes on Cooley Investigation"

Speaker: Don Schanche

I'll be making notes from "Confidential and Privileged Report of Special Committee to the Board of Trustees, Baylor College of Medicine." Subtitle: "To Investigate Clinical Application of Artificial Heart at St. Luke's Hospital, Houston, Texas, April 4, 1969."

The report opens with a conveying letter from Dr. Hebbel E. Hoff, M.D., Ph. D. for the Special Committee reaching two conclusions:

- 1.) Funds from the National Heart Institute were used in the development of the artificial heart used in the recent operation involving the patient Karp.
- 2.) Guidelines for projects involving human beings were not followed.

Date on Hoff's note: April 18, 1969.

Followed by a letter April 8, 1969, from Dr. Theodore Cooper, M.D., Director of National Heart Institute addressed to Mike DeBakey raising the question of new reports that the artificial heart recently implanted clinically by Dr. Denton Cooley:

"Our grant records indicate that Dr. Liotta's, that is Dr. Domingo S. Liotta... Our grant records indicate that Dr. Liotta's salary and to a substantial

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degree his research was supported by Grant HE05435. This being the case, I would like to request that the Institute be provided with summary data on the test and evaluation of this particular device in animals prior to clinical application. Also, as you know, current departmental guidelines require that projects involving human subjects be approved by a local committee for human investigation. Was the protocol for the clinical application of this device reviewed by your local committee?

Sincerely yours,

Theodore Cooper

I presume it was Dr. Cooper's letter that gave the impetus to this Committee.

Quoting an excerpt from a newsletter called "Drug Research Reports," April 16, 1969:

"A controversy developed over whether Dr. Cooley was obliged to follow federal guidelines by submitting to a review board his plan to use an artificial heart. Dr. Cooper of N.H.I. wrote to Dr. Michael DeBakey, President of Baylor (where Cooley is a surgery professor and holder of a two million plus federal program project grant for artificial heart development) to determine

if the device used was made in DeBakey's laboratory under grant support and if so federal guideline procedures were followed. There are one hundred and thirty different projects going on under the DeBakey money.

... Cooley who has not been a Heart Institute grantee since fiscal year 1967 denied any use of federal funds on the device he used. The device, however, was designed by Dr. Domingo Liotta of Baylor, a current recipient of N.H.I funds. Liotta said the device Cooley used was developed from Cooley's Texas Heart Institute funds rather than federal money. Cooley said he and Dr. Liotta started working on their device four months ago in the Baylor surgical lab, the same lab DeBakey uses. He said Liotta and DeBakey were working on a bypass of the left ventricle, the heart pumping chamber, not a total replacement of the heart with an artificial organ. That was not being studied until Cooley sought Liotta's advice, Cooley added.

Since Cooley is not now a federal grant recipient, N.H.I has no control over his actions. However, if it is determined federal funds were used, N.H.I could take some remedial action against DeBakey. That could range from a mild rebuke for not following the rules to cutting off federal funds entirely."

Guidelines for getting permission to use human subjects for research are in a policy memorandum dated November 4, 1968:

To All Faculty Members

From Harold Brown, M.D., Chairman, Committee on Research Involving
Human Beings

"If human beings are to be used in any study, an application for approval by the above Committee should be submitted to Dr. Harold Brown, Chairman, Committee on Research Involving Human Beings, Room 6-4, Ben Taub General Hospital. The application should be prepared in narrative form, (eight copies:) following the outline set out below. "

The outline asks such things as:

- 1.) Describe your methods of obtaining informed consent of your human subjects.
- 2.) Describe succinctly the procedures to be used on your human subjects. Indicate any known human risks involving them..involved in such practice as experimental medicine or surgery and describe what safeguards you will maintain for the protection of your subjects.
- 3.) Indicate the potential benefits to be gained from this experimentation.
- 4.) Demonstrate your procedures for protection of the individual privacy of your human subjects. If the project includes administration of personality tests, inventories of questionnaires, etc., explain how the informed consent of your subjects is obtained or why such

is deemed undesirable in this project.

- 5.) The P.H.S. now has a very strict requirement that the College exercise "continued surveillance" over research involving human beings. Therefore, along with items one to four above include the following statement:

"I certify that I will strictly adhere to the protocol of procedures described in this application for research support and will not alter those procedures in any way concerned with human beings without prior consent to and receipt of approval from the Faculty Committee on Research Involving Human Beings."

Among other things, this form must be signed by the department chairman's signature, which in this case would have been Dr. DeBakey.

The Committee under Brown includes George Clayton, M.D., David Freedman, M.D., Montague Lane, M.D., Arthur Beall, M.D., Harry Lipscomb, M.D., Carlos Ballbona, M.D.

In addition to that committee, there is also a Medical Research Committee at St. Luke's Hospital which supervises and monitors medical research at St. Luke's.

Also, the Public Health Service Grants for Research Projects Policy Statement revised July 1, 1967, issued by U.S. Department of Health, Education and Welfare Public Health Service says..begins:

"Safeguarding the rights and welfare of human subjects involved in investigations supported by Public Health Service Grants or Awards is the responsibility of the grantee institution. This responsibility includes assurance of adherence to the loss of the community in which the investigations are conducted and due consideration to pertinent ethical issues."

Quoting from a statement by DeBakey made to the Executive Committee of the Board of Trustees on April 10, 1969, in which he opens by saying: when he returned home from a trip to Washington on Monday, April 7, after a meeting on Saturday, April 5, in Washington, Ted Cooper called and asked the questions which he subsequently repeated in his letter.

"I then asked Dr. Cooper," quoting now from DeBakey's statement, "if he would write me a letter confirming his requests." (Scratch preceding)

"I knew nothing about this matter until the news was released Friday evening, April 4th after I arrived in Washington and had checked into my hotel. I left Houston Friday afternoon for Washington to attend a meeting of the Artificial Heart Myocardial-Infarction Advisory Committee of the National Heart Institute

of which I am a member. At the meeting on Saturday morning April 5th Dr. Cooper and other members of the committee naturally discussed this development and it was apparent from Dr. Cooper's remarks that the artificial heart implanted by Dr. Cooley was similar to that which we had developed in our laboratories in his opinion. Dr. Cooper had visited us about two weeks before Dr. Cooley's implantation. At that time, he came here to inform himself personally of various aspects of the research work we were doing under this grant in order to give us as much help as he could before the occurrence of an elaborate project sight visit scheduled May 7-8 in regard to renewal of our grant of almost three million dollars. He therefore came down for a one day visit with us and I took him around to the various research laboratories supported by this grant, one of which was the laboratory at Baylor engaged in the artificial heart program--the artificial heart program. I showed him the various aspects of the artificial heart research activities in the laboratory, including the fabrication of the pump and some of the problems that we had encountered in its design and development, including some of the results in our animal research work.

I had him meet Dr. Liotta in the laboratory and had Dr. Liotta show him various aspects of the fabrication of the pump, including certain modifications

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we were in the process of making in the pump for better attachment in the animal. Since we had had some disastrous technical problems in experiments in which we had tried to use it."

Farther down on the same statement:

"I am sure that you realize that I am in a rather difficult position to make any public statements since I am not only the principal investigator of the artificial heart program, but as President of the College, I'm also the responsible executive officer of the College. I therefore considered, if necessary, for me to remain aloof from the public controversy and make no public comments or statements. For this reason, I believe it is necessary to establish the proper procedure to investigate the facts that have taken place in this matter."

Farther down:

"For your information, too, I may say that all of our affiliated hospitals also have established special committees for research involving human beings."

Asked by Mr. McCollum to capsule the events as he knew them, DeBakey says that:

"About three or four months ago Dr. Cooley went to see Dr. Liotta and discussed with him the possibility of working together to develop an

artificial heart for use in human being."

Paranthetically, the Advisory Committee has discovered this. He's quoting the Advisory Committee.

" Dr. Liotta when asked by the Committee why he did not come to me who he knew was responsible as the principal investigator stated that he deliberated about this, and although realizing that he was doing wrong, talked it over only with his wife and agreed to go along with Dr. Cooley. He stated that he made this decision because he felt that Dr. DeBakey would not allow this device to be used in human beings and that Dr. Cooley was determined to apply it in human beings."

A fascinating little thing here:

"The second factor we know about is that Dr. David Hellums who is the principal investigator for the Rice University artificial heart grant which is a companion grant to our own called me and said he was shocked to hear the news of the artificial heart implantation by Dr. Cooley. We have been collaborating with the group working on the Rice artificial heart program since 1964. Dr. Hellums then told me that about two months ago one of his men, Mr. Bill O'Bannon, an engineer on the part-time faculty of Rice and salaried by the Rice grant, came to see him to say that he had had a confidential inquiry about

building the driving and control mechanism for the artificial heart..for a artificial heart similar to that which Rice had developed for use in our experimental laboratory. When Dr. Hellums asked him who the person was Mr. O'Bannon stated that he had been asked by the party not to reveal his name. Dr. Hellums told Mr. O'Bannon that he could not approve doing this from the Rice standpoint, but that if Mr. O'Bannon wanted to do it on his own time and work through the Texas Instruments Company apparent of which Mr. O'Bannon is part owner and parent, he would have to do it on this basis. Dr. Hellums later learned that Dr. Cooley was the one who asked Mr. O'Bannon to build the pump. He discovered this when Mr. O'Bannon came to see Dr. Hellums on Thursday, April 3rd, the day before the implantation by Dr. Cooley. and asked permission to run the pump for Dr. Cooley in the operating room the next day. Dr. Hellums told Mr. O'Bannon he could not give this permission. On Friday morning, the day of the operation, Dr. Cooley himself called Dr. Hellums to ask his permission to let Mr. O'Bannon help run the pump, which he planned to use in a patient. Dr. Hellums told Dr. Cooley that he could not give his approval because he did not have Dr. DeBakey's approval for it, nor did Dr. Cooley have such approval, since Dr. Cooley admitted to Dr. Hellums that he had not obtained Dr. DeBakey's permission. Dr. Hellums explained

to Dr. Cooley that since they had not tested this pump, they could not be responsible for running it. Moreover it would take more than twenty-four hours to test the pump." That's also from DeBakey's statement to the Trustees.

A side comment by DeBakey:

"For your own background information regarding my relationship to the development of this pump, let me state that I first became interested in the development of the artificial heart more than a decade ago and made strenuous efforts through the National Institutes of Health and through Congressional testimony to obtain support for work in this field. Indeed, it was on the basis of my testimony to Senator Lister Hill that funds, finally...funds were finally allocated in 1964 for this purpose."

Dr. DeBakey says then he went to Dr. Pitser at Rice and told him they were getting funds and asked to establish a collaborative program. Dr. Pitser agreed.

"In 1964, I appointed Dr. Liotta to the program as an assistant and Dr. William Hall as the director."

Their first efforts were on a complete artificial heart, but then they pulled back to a pump that could be used as quick failing left-ventricle."

"Which research work ultimately led," now quoting, "This research work ultimately led to the development of the left-ventricular bypass pump

which was thoroughly tested on hundreds of animals to establish its safety and effectiveness. Thereafter, in 1966 we applied it in a series of critically ill patients. It showed its value in these patients. We then continued to modify this pump in the hope that we could improve its design and also directed our efforts to more intensive study of the blood interface problem, etc."

"As we progressed with the changes in the design of the pump, we evolved a biventricular type of pump in September 1968, which is essentially similar in design to that used by Dr. Cooley in his clinical experiment. Our pump was tested in the laboratory from both hemodynamic and design standpoints at both Baylor and Rice. In the early period of January 1969, I authorized Dr. Hellums of Rice and Dr. Liotta of our laboratory to begin some experimental animal work on this pump. The purpose of these experiments was to determine the technical feasibility of its replacing the heart, to develop design modifications that would permit its proper technical and anatomic application in the animal, and to study certain physiologic criteria that might be used in the proper control of the dropping mechanism in the pump."

"The first four animals in which the pump was applied died on the operating table from various technical problems. As a result of this experience, certain modifications were made in the design of the pump for its proper attachment. These proved to be successful and in the next three animals it

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was possible to apply the pump technically, but the pump did not prove successful in maintaining viability of vital organs in any of these animals. One survived twelve and a half hours and died from rupture of the pump. This animal showed some reflex movements. . . This animal only showed some reflex movements, but was unable to stand and showed no kidney function. The second animal in this series survived about eight and a half hours and only showed some reflex movements, was unable to stand, and showed complete renal failure with progressive anoxia indicating lung congestion and failure. The last animal in the series showed no evidence of viability from the time of the artificial...from the time the artificial heart was implanted, until the pump was discontinued forty-four hours later. The animal was essentially a cadaver in which the pump continued to pump blood which was then coagulated by Heparin."

"All scientific research workers in this field have long known... (This was a paragraph from the last thing I read in.)

"All scientific research workers in this field have long known that the artificial hearts that have been developed by various investigators have all had the same problem in their application to animals, namely that while it is possible to obtain some evidence of survival of animals for periods ranging up to about two days, there develops progressive damage to the blood resulting in irreversable damage to vital organs, such as the brain, kidneys, and lungs

producing death from this damage."

In answer to a question: "Could you use it to keep a person alive for two days in the hope that you could save his life until a heart is available?"

DeBakey replies, "It is important to recognize the fact that on the basis of our experimental evidence it is not possible that this artificial heart can keep a patient alive in sufficiently good condition for two days to permit recuperability of the damage that takes place over this period to the vital organs, such as the brain, kidneys, and lungs. Moreover, the ethics may be questioned of applying a procedure such as this in a patient without animal evidence of its safety and effectiveness--on the basis that it might keep a patient alive until a heart donor can be obtained for transplantation--since it is also not possible to know that such a donor heart will become available for this purpose."

Farther down:

"It should be observed that the patient's clinical response to the artificial heart was much the same as observed previously in animals, with progressive damage to the kidneys and even to the brain resulting in complete renal failure at the time the transplant was performed and complete brain failure, since this was developing progressively and the patient never regained

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consciousness after the first heart transplantation was performed."

End DeBakey's statement.

Quoting now from Document III. - A: "Account of Preliminary Investigation of Application of Baylor Heart Pump in Man." This recounts that an emergency meeting of the committee was called after the...they.. After local newspapers reported Cooley's operation. After informal discussion, they called a formal meeting of the committee which officially approved an official report. On Monday afternoon Dr. Hoff requested Dr. Domingo Liotta to meet with Dr. M. E. DeBakey and Dr. Joseph Merrill to discuss this matter. The following facts were established:

- 1.) The pump in question had been developed in the surgical laboratories of Baylor College of Medicine under the auspices of the Cardiovascular Research and Training Center grants-- HE09252 and HE05435.
- 2.) Dr. Liotta admitted that Dr. Denton Cooley came to him about four months ago to ask him to collaborate with Dr. Cooley on use of this pump in a human being. Dr. Cooley instructed Dr. Liotta not to inform Dr. DeBakey about this plan. Dr. Liotta

discussed this matter with no one but his wife. And after due consideration agreed to the collaboration.

- 3.) Dr. Liotta admitted he was aware of his responsibility to inform Dr. DeBakey. Etc.
- 4.) The actual pump used in the clinical trial at St. Luke's Hospital was taken by Dr. Liotta from the surgical laboratories at Baylor to St. Luke's Hospital for implantation then.
- 5.) Dr. Liotta admitted that the control system which was purchased commercially is virtually identical to the one developed at Baylor and Rice University. The exact date it was ordered was not established at that time.
- 6.) Dr. Liotta said that he had no knowledge of the requirements of the Baylor Committee on Research Involving Human Beings nor of any obligation devolving on him because of this poor financial Heart Institute grant. Etc. "He did not discuss these points with Dr. Cooley."

Dr. Liotta's title was Assistant Professor of Surgery and Assistant Professor of Anatomy at Baylor.

"The Cooley implant," quoting from the report of the..Harold Brown's Research on Human Beings Committee says:

"Implantation is reported to have been carried out by Dr. Denton Cooley, Professor of Surgery, and Dr. Robert D. Bloodwell, Assistant Professor of Surgery of this College."

"Approval of the Committee on Research Involving Human Beings for the clinical trial of the device in question was not obtained and no protocol or application has been submitted to the Committee."

The O'Bannon should be identified as Texas Medical Instruments Company, not Texas Instruments Company.

The Advisory Committee of N.I.H. grant HE 05435, which is the one I was just reading, or ..No, I guess I didn't. No, the one I got the Texas Medical Instruments Company. On April 8, 1969, recommended that N.I.H. be informed immediately that Domingo Liotta without your knowledge or that of any member of the Advisory Committee took action described above purposely with all the information pertaining to the plans for the use of this device in a human subject and did not seek approval of Baylor's properly constituted Committee on Research Involving Human Beings. The committee further recommends that Dr. Liotta's employment on this grant be terminated

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immediately and that the National Heart Institute be apprised of this action.

Document IV. "Summary of Dr. Liotta's Participation in the Clinical Application of the Artificial Heart at St. Luke's Hospital." It's an eight-part outline summary--at the bottom dated 4-10-69, with the legend:

"I agree with the above statement!" Signed,

Domingo S. Liotta, M.D.
Assistant Professor of Surgery
Baylor College of Medicine
Houston, Texas

Witnessed by: Hebbel E. Hoff

Joseph M. Merrill

- 1.) Dr. Liotta holds a full-time appointment as Assistant Professor of Surgery and Assistant Professor of Anatomy at Baylor College of Medicine.
- 2.) His appointment to the Department of Surgery has been for the purpose of assisting in the development of an artificial heart under the auspices of the grant from the National Heart Institute and under the direction of Dr. M. E. DeBakey.
- 3.) Approximately four months ago, Dr. Denton Cooley invited him to collaborate in the development of an artificial heart for total replacement.

- 4.) The artificial heart used by Dr. Cooley was constructed by Dr. Liotta in the surgical research laboratories at Baylor College of Medicine.
- 5.) Between the time of preliminary discussion and actual use, seven animal trials were conducted in the surgical research laboratories at Baylor College of Medicine using a pump similar in design to that employed later at St. Luke's Hospital.
- 6.) The experimental details of these trials will be supplied to the Cardiovascular Advisory Committee by Dr. Liotta.
- 7.) Dr. DeBakey was not informed of the collaboration with Dr. Cooley.
- 8.) The institutional guidelines pertaining to human research.. human subjects were not discussed during the period of experimental work.

The next Document V. - A. are four progress reports to Dr. DeBakey by Dr. Hall and Dr. Liotta. The four reports this section contains are dated August 29, 1968, and covers basically that they're using Dacron velour lining and using a diaphragm-type modification of the whirl pump. Studies on total

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heart replacement were continuing. A double pump was to be placed in the artificial circulation system. Anatomical studies begun on methods of attachment of artificial heart to stump of amputated heart.

September 17, 1968: Further studies on total heart replacement.

October 28, 1968: Diaphragm-type pump decided upon. Further studies on velour-lining of pump. Studies on valves. Heterograph versus homograph. Control systems need more study.

December 18, 1968: Total replacement pump of diaphragm-type ready to implant in pig. (Orthotopic equals implanted in the normal position of the heart in the body.) 2. Need for control systems.

These reports are addressed to Dr. DeBakey from Drs. Hall and Liotta. They give various technical information about the work and the pump and the fabrics, materials, fabrication techniques. Report on some dog experiments with the pump, but they don't really say too much. What kind of success. There's no detail on how long the dogs lived.

In the October 28th report from Dr. Liotta alone to Dr. DeBakey says:

"Pump designs for an orthotopic cardiac prosthesis are moving very rapidly. After a crude evaluation of a prototype, all proposals are submitted

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to you for final approval. In the past few weeks we have switched from the ventricular-shaped pump which proved to be potentially dangerous in clotting and excessive fibrin formation in the apex area to a diaphragm-type of pump with whirling blood functions.

Next is Document V. - C. I'm going to ask Mike DeBakey to make a copy of it for me. It's Cooley's report on the artificial heart implantation. And in discussing the patient he says, "The patient was opposed to a cardiac transplantation which was considered the procedure of choice and desired a mild cardio-excision with ventriculoplasty--a procedure which he knew from news reports."

A technical paper called "Orthotopic Cardiac Prosthesis" about the Baylor artificial heart program with Dr. Liotta as senior author was on the verge of publication by the American Society for Artificial Internal Organs in its journal Transactions and for presentation to the society's meeting. DeBakey withdrew that paper by telegram on April 17 and sent a copy of the telegram to Dr. Liotta. It was too late to get it taken out of the formal program of the committee, however, which listed it as to be presented at 10:15 a.m.: "Orthotopic Cardiac Prosthesis", Tuesday, April 22, 1969. His co-authors were W. O'Bannon, L. Feldman, H. Bourland, S. Calvin, and M.E. DeBakey.

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Document VI. is a sort of table of contents--list of statements of witnesses. Name, date of appearance before committee: Mrs. Suzanne Anderson, Dr. Robert Bloodwell, Sam Calvin, Dr. Denton Cooley, Louis Feldman, Dr. William C. Hall, Dr. Grady Hallman, Dr. J.D. Hellums, Dr. Domingo S. Liotta, Gerald Maley, Bill O'Bannon, Dr. Brantley Scott, Polk Smith.

The statement of Mrs. Suzanne Anderson, plastics technician, in the Baylor surgical research laboratories. It said she made the particular pump in March, 1969 and determined that "since that is when we began using the cuff-type of connector. When Dr. Liotta asked me to put the Dacron velour on the tubing, I knew it was for human use, since we did not do that for animal use. When I was fabricating the pump, Dr. Liotta became very angry with me because of the way I was lining the pumps and he said that I was going to kill someone since the lining was not perfect and did not come up far enough. The last three pumps that I made, I knew would not go into animals because Dr. Liotta continued stressing the importance of perfection and continually told me that I would kill someone if the pumps were not perfect. These comments began about three or four weeks ago and continued up until about two weeks ago."

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Farther down:

"We have made approximately fifteen or sixteen pumps with Dacron lining and of those three are still unaccounted for."

A little farther down:

"We had been given a deadline by Dr. Liotta--this was approximately March 20 he gave us--and he said he must have three perfect pumps with the Dacron lining. Dr. Liotta wanted me to come in every Saturday in March to work on these pumps and I came in three of these."

Farther down:

"On the last Saturday in March, I gave Dr. Liotta the various parts for fabricating of these three pumps--the domes and bodies with lining. He personally put in the valves, the diaphragms, and assembled the three pumps. I did not see them again after giving him the component parts, but all of us in plastics did see them as he was putting them together, but not after that. It was unusual for Dr. Liotta to assemble the component part into the total heart. We normally do that in the plastics fabrications shop and have always. This was the exception."

This statement made by her on April 15--notorized and sworn. That's Suzanne Anderson.

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From the statement of Sam Calvin on 4-12-69 it was apparent that the department, in answer to a question about how long has the department been working on a dual-ventrical pump, he says:

"Actively over about six months."

In answer to another question,

"I assumed that since Dr. Liotta had been the director it was legitimate. At the last I was not sure, because I was told not to reveal it to anyone. I was told it should be kept secret."

Question: "Who said this?"

"Dr. Liotta."

And now the statement by Denton Cooley which I'm going to ask Mike to copy for me. It sounds fascinating. Cooley's statement taken April 12, 1969. He hesitates, halts, , denies that there was anything wrong. Says, "Real...really..it wasn't..it was not our purpose particularly to develop an artificial heart. This was really secondary. What we wanted was a resuscitative type of pump which would give us time, so we could secure a suitable."

He claims Liotta did work on nine calves and he stumbles around about thinking he paid for it from some research funds he has.

He says, "We have around eight thousand to ten thousand dollars per

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year. We tried to make this project independent of H. H. I. funds," he says. He claims his pump was different, even though the only difference appears to be that he used something called a "wada" valve, which I gather is a flat valve. It's W-A-D-A.

Apparently they worked entirely on the left-ventricular bypass for most of the early years of the artificial heart research program until about mid 1968 at which time they, under DeBakey's direction, decided to go full blast for a total artificial heart.

Mr. Louis Feldman, who is head of both the plastics and the machine shops says:

"If someone were to start building these, that is the pumps now, it would take four to five months."

When asked, "Is there any significant difference between this (that is Cooley's pump) and yours?"

He says, "This is ours. This is the Baylor pump."

Asked "How many pumps were there?"

"We can account for seven and there are three unaccounted for. The process of vulcanizing the pumps is done in the steam autoclave. Therefore, when the last step is completed, the heart is automatically sterile. Dr. Liotta

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was doing the final assembly. We made the parts of three more that we cannot account for. We made the parts for three more that we cannot account for. I'm not absolutely sure it was three. It may have been two."

QUESTION: Who would have them?

FELDMAN: Sometimes we might give them to the scrub technician.
There is no fixed pattern.

QUESTION: If you made the parts, would Dr. Liotta be able to put them together?

FELDMAN: Yes.

QUESTION: Do you put the valves in?

FELDMAN: Dr. Liotta put the valves in.

Louis Feldman.

Feldman also in a separate statement says:

"I did not see the pump that Dr. Cooley used on Mr. Karp, but I feel sure that it was made in our laboratory. It represented the work of four machanists, three plastic technicians, plus lab technicians, totaling over twenty people. Above all, it represented the work of Dr. Liotta who did work Saturdays and Sundays and did himself fabricate diaphragms and make the final assembly of the pumps. We in the laboratory helped Dr. Liotta and followed

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his instructions because it was the wish of Dr. DeBakey that we do so. If Dr. DeBakey had ordered the work stopped, the work would have been stopped."

Dr. C. William Hall who headed the program and was director for some time in his statement said he had not seen the pump until now. Noted some slight differences in it and then says, "The design of this particular pump arose in this artificial heart project while I was still director as a team effort along with Dr. DeBakey as the principal investigator.... If anyone asked me, I would say 'yes, this is the Baylor-Rice artificial heart'."

April 11, 1969.

Statement by Dr. Grady Hallman on April 12th which he sort of takes a "I just work here" approach. He says, "Dr. Cooley takes care of things like the Committee on Research Involving Human Beings." And he just assumes everything is taken care of and does his work.

Statement by J. D. Hellums, Ph. D., Professor of Chemical Engineering, Rice University taken on April 12, 1969 recounting how Mr. O'Bannon came to him telling him that he had been approached by an individual--didn't want to be identified--who wanted the power unit--wanted a power unit like the one they had developed. He said, "I suspected, of course, that it was Dr. Cooley

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and I had no objection to him or any other qualified person having the unit, providing (as he explained) that O'Bannon did it on his own time. .. Then it was delivered on Wednesday, two days before the operation. On Thursday, the day before the operation, Mr. O'Bannon came to me and said Dr. Cooley and Dr. Liotta were planning a total replacement on a person the next day. Mr. O'Bannon was obviously extremely upset. He said he had told them he could not participate unless it was cleared with me. He further asked me to say "no." Dr. Cooley talked to me the following day and said, (quoting Cooley),

"We hope we won't have to use this device, but we are afraid we might have to. Could we use some of Mr. O'Bannon's technical expertize." I said Mr. O'Bannon could not for the following reasons: Our relationship with Dr. DeBakey. I understand it has not been cleared with him. I cannot do it unless we do it in an open way. Two: Even if Dr. DeBakey were in favor of it, we couldn't cooperate on such short notice. In our previous clinical work with Dr. DeBakey, we developed the policy that we would not use any of these pumps unless they had been tested on a circulatory system simulator in our laboratory for proper function. I do not know how frank Mr. O'Bannon was with you, but I want you to know what he thinks. He has sincere doubts as to whether this pump has been properly tested."

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Dr. Cooley said, "It has been running over here for many hours and it looks good."

"Three, if you do have success" (this is Hellums talking to Cooley), "since the unit has manual, not automatic control only you have to have a staff to monitor the unit for days or perhaps weeks or months."

"He said again that he was hoping he would not have to use it and that he understood my reasons for not wanting to be involved. I requested that if he did use it, please not mention Rice at all, but say the power unit came from O'Bannon or his private company. We have tested many of these pumps. Sometimes they leak and do not work. O'Bannon had not seen the pump and he had not tested it. The circulatory system simulator puts the same pressures on the pump as the human system, as best we can do in vitro. We do not want to be involved for many reasons. One reason is that we did not have positive first hand knowledge that it was properly tested."

That's the power system, I presume, he's talking about.

Domingo Liotta's statement to the committee on April 10, 1969: He says...He concludes his statement. I'm going to ask Mike for a copy of the whole statement. He concludes the statement with, "I believe he (Cooley) has the right to do anything to keep a patient alive."

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QUESTION: Whose orders brought the pump from Baylor to St. Luke's?

LIOTTA: I brought them and left them in my briefcase all these days.

Domingo S. Liotta, M.D.

This statement is not notarized.

In O'Bannon's statement on April 12, 1969, he says,

"On the 17th of January I was asked if I could build a power unit. I said I could, but I did not know whether it would be proper. Dr. Liotta approached me. He was speaking for Dr. Cooley. He said it was Dr. Cooley's idea."

Later he says, "The monitoring equipment is the same. The power unit is a direct descendant of the unit developed at Rice. The parts are different but the function is the same."

Asked, "When did you deliver the unit to St. Luke's?"

O'BANNON: "On April 2nd. I believe it ran all day April 3rd. I understand it ran all day and did not break down. In the specifications I wrote and gave Dr. Cooley, I stated it was for animal experimentation only and not for human use. I am not sure I would have built it in the case."

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O'Bannon apparently did not go to the operation, but a man named John Manness, president of Texas Medical Instruments, was there. While O'Bannon is a director and stock holder, he said he didn't want to go. Let's see. He says....

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Repeating that from the other side:

QUESTION: Were you consulted about John Manness being at the operation?

O'BANNON: I was asked what I knew about the situation. I was asked to be there and I refused on instruction by Dr. Hellums.

The statement from Dr. Brantley Scott, M.D., April 12, 1969. He was chairman of the Committee on Research Involving Human Beings at St. Luke's Hospital. He says he's been chairman of the committee since January 1968 "and to date I have seen no protocol on this project...I have read the minutes and there is no mention of such a protocol. Three other protocols have been received by the committee from Dr. Cooley, but none has been received from Dr. Cooley on the use of an artificial heart."

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Statement by Polk Smith, supervisor of surgical research laboratories, Baylor College of Medicine. States in latter part of 1961 the program began under Dr. DeBakey's direction. Funds from 1961 to '64 came from various surgery department grants. In June 1964 first federal grant for working on the artificial heart was first started under Dr. DeBakey's direction. From this time to the present all work done has been charged to the federal fund. Smith says that two.. She sights them by number:

"Two calves used by Liotta. Calf #4583 on February 20, 1969, and Calf #4584 on February 24, 1969, were both charged to the artificial heart program. On February 25, 1969, a memorandum from Dr. Cooley to Mr. A. O. Johnson of the Baylor business office requesting that Dr. Liotta charge expenses incurred in the surgical cardiovascular laboratory to his Huntsville Heart Research grant and to his Weimer County Research grant. The vivarium (whatever a vivarium is) was notified of this on March 13 by Dr. Liotta and Calves #4583 and #4584 (which were the ones she just mentioned) were then transferred to the two respective grants. This information was called to my attention April 9, 1969. During the last week of March and the first week of April...

Oh, previously, Smith notes that she actually observed the February 24th experiment on calf #4584 and was present while movies were being made in

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the Taub Lab by surgery photographers in the presence of Dr. Liotta, Dr. Cooley, Dr. Jim Ross, Mr. Lou Feldman, and myself. I reported this to Jerry Maley on February 23rd in person. During the last week of March and the first week of April, three artificial hearts were completed by the laboratory staff and turned over to Dr. Liotta. This has been a routine procedure since 1968. These three artificial hearts are now missing from the laboratory. "

Cooley paid \$176.75 for Calf #4583. That was \$125 sale price, plus \$51.75 in board. Calf #4584--sale price \$125. Total board \$45. For a total of \$170. She charged them to his two research funds--the Weimer, containing \$289.38 balance and the Huntsville containing a \$312.04 balance. That's in a letter from Cooley to Mr. A.O. Johnson, business office, Baylor University College of Medicine, 1200 Moursund Ave., Houston, Texas, 77025, February 25, 1968.

The board charges of Calf #4583 were later readjusted to \$33.75, making that calf a cost of \$158.75. The other one remained the same.

Polk Smith is apparently Miss Polk Smith. She is so identified in a statement she made on April 11, 1969. She notes,

"In my opinion none of the operations could be considered a success. None of the calves were ever ambulatory. "

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Farther down in her statement:

"I was informed that two of the pumps were gas-autoclaved about 5 p.m. on Thursday evening, but the two pumps were not there on Friday morning when my employees came to work in the laboratory. To my knowledge no one in the laboratory had any idea that the pump was to be used in a human being. "

Odds and ends from a letter to Dr. Hoff from Dr. Robert O. Morgen, M.D., Chief Renal Section, Internal Medicine Service, Methodist Hospital who was called to the bedside of Haskell Karp on April 7 at 2:30 p.m. by Dr. Don Rochelle who requested that "I see the patient in consultation with regard to severe oliguria and increasing hyperazotemia. I entered the operating room where Karp was being kept. At 3 p. m. joining Drs. Rochelle and Don Bricker. And about twenty minutes later were joined by Dr. Robert Bloodwell. We reviewed the patient's history and just radiographs. I was informed the implantation of the artificial heart had been performed between approximately 3 p.m. and 6 p.m. on April 4, 1969. And he underwent cardiac homotransplantation between the approximate times of 6 a.m. and 11 a.m. on April 7th!" The operation being four hours prior to his consultation. The patient had been virtually anuric, that is he had urine flow rates of 0 to 4 ml. per hour. The highest twenty-four hour urine volume being 88 ml.

DR. MORGEN: "I found the patient semi-comatose with pupils in mid position poorly responsive to light stimulation. The face was dusky, suffused and puffy. The neck was thick and puffy and I could not evaluate the external jugular veins."

From what he says it almost sounds as if Haskell Karp was lying there dead plugged into machines to keep some signs of life going.

Dr. Morgen left the operating room at 3:50 p.m. Stayed in telephone touch. The patient remained completely anuric, "such that I was not even able to obtain a urine specimen for further diagnostic examination...I understand that the patient expired 3:15 p.m. on 4-8-69.

Following are the conclusions in the report of the committee as stated in their kind of a rough copy in which they're listing the documentation for each of these statements. I won't read the documentation, I'll merely read the statement.

"The artificial heart implanted in patient Karp by Dr. Cooley on April 4, 1969 at St. Luke's Hospital is a product of the Baylor College of Medicine Artificial Heart Program which since 1964 has been supported by funds from the National Heart Institute with Dr. Michael DeBakey designated as principal investigator. The artificial heart used by Dr. Cooley in patient Karp on April 4, 1969..." Nope, this is saying the same thing here.

Liotta admitted that pump was designed and developed in Baylor surgical laboratories. Dr. DeBakey was deliberately kept uninformed of the collaboration of Drs. Liotta and Cooley and of their contemplated clinical use of the artificial heart developed and fabricated under Dr. DeBakey's direction. Drs. Cooley and Liotta deliberated conspired to keep secret from Dr. DeBakey their intent to use the artificial heart on a patient, despite their knowledge that he was the responsible investigator of the Baylor Artificial Heart Program. Drs. Cooley and Liotta planned in advance to use the artificial heart developed and fabricated at Baylor under Dr. DeBakey's direction in patient Karp. Personnel and facilities of the National Heart Institute Artificial Heart grant with Dr. DeBakey as principal investigator were used by the animal experiments in which the artificial heart in question was used. Only seven animal trials with the device Dr. Cooley used in Mr. Karp preceded the human experimentation by Dr. Cooley, and none of the experiments were successful. Drs. Cooley and Liotta failed to observe the Baylor requirement that all clinical experimentation must first be approved by the Committee on Research Involving Human Beings. Drs. Cooley and Liotta failed to observe the St. Luke's requirements for human experimentation.

There's a letter here from DeBakey to Dr. Harold Brown recommending against approving a Cooley proposal in July, 1969, for going ahead with doing

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more human research with the same stuff, apparently. In which DeBakey reviews some of the history of this including an accusation that Liotta falsified his animal data in that original article which was pulled from Transactions. I'm going to ask Mike to make a copy of this for me so I won't make notes on it.

Switching now to the General Files, there is a letter from Liotta to a Dr. John D. Turner, editor of Cardiovascular Research Center Bulletin, Baylor College of Medicine, Houston, 20 June 1969, complaining about DeBakey's stealing his notes to write a paper for the journal. That's the paper about the animal experiments.

Next the sign of great innocence. Rear Admiral V.S. Fahrney, U.S. Navy retired, Secretary Committee on Science and the Arts, The Franklin Institute writes DeBakey on May 21, 1969 saying that they are beginning to look into Dr. Domingo Liotta as a possible recipient of the Franklin..of an award of the Franklin Institute for his successful work--there's some irony in this letter--for his successful work in developing a mechanical heart that "that was recently successfully implanted in the chest of a human being."

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A letter from DeBakey to the Secretary of the International Cardiovascular Society strongly recommending against granting membership to Liotta:

"On the basis of recent developments here I strongly recommend that he not be considered for admission to the Society. Incidentally, he has listed erroneously as co-director of the Baylor Artificial Heart Program which is under my principal investigatorship. Until last month, his title was assistant and he has never been co-director.

Yours sincerely,

Michael E. DeBakey, M.D.

April 16, 1969: DeBakey's letter to Liotta relieving him of his.. of any further involvement or participation in the heart research project.

Here is the source of Domingo Liotta's lie in the abstract of his paper on orthotopic cardiac prosthesis which he sent in in order to get the Society interested in publishing the paper. He makes the statement in describing his experiments: "...and in ten calves total replacement of both ventricles was carried out for twenty-two to forty-four hours with the animal standing normally." That statement is not true as DeBakey points out later in a personal and confidential letter to Dr. Robert Liebelt, Chairman of the

Department of Anatomy, Baylor College of Medicine, Houston, in which he is recommending that Liotta not be reappointed to the faculty. He repeats that quote then says, in DeBakey's letter says, "Since the first calf experiment did not take place until January 30 and since there were only seven experiments in calves, none of which was able to stand normally, this statement in the abstract is a falsification of the data. The abstract was submitted by Dr. Liotta without my knowledge or consent and in direct violation of specific instructions to him about such material. I learned of the abstract only after I saw the Society's program for the meeting in April. At that time I withdrew the paper from presentation."

This is an article that ran Thursday, May 22, 1969, in the Washington Evening Star. By Judith Randall in a column called Washington Close-Up: Cooley Transplant Demands Answer: It is essential that all facts surrounding Dr. Denton A. Cooley's activities at Baylor College of Medicine in Houston be speedily disclosed. The reason is unless the public is fully informed about the sequence of events that led the Texas surgeon to implant an artificial heart that was.... --Oh, scratch all that.

Cooley's request in July of 1969 to the Committee on Human Research was just blocked cold because DeBakey wouldn't sign it and by the rules as Dr. Brown points out in a letter to Cooley, July 7, 1969,

"According to the guidelines of the Baylor Committee on Research

Involving Human Beings the protocols must be signed by the appropriate departmental chairmen for consideration by our committee. The protocol can be considered as soon as this requirement is met.

Yours sincerely,

Just blocked him cold.

A letter to Dr. Theodore Cooper from L. F. McCollum, Chairman of the Board of Trustees reporting on the progress of Baylor faculty members signing a letter affirming their compliance with the rules of the Committee on Research Involving Human Beings in which out of some 500 full-time salaried faculty and 900 clinical faculty members who have no paid appointment but have contributed their services:

"It should be noted that only one objection has been raised to the signing of the letter and that was by Dr. Denton Cooley. Dr. Cooley has resigned from the faculty of Baylor College of Medicine and his resignation was unanimously accepted by the Executive Committee of the Board of Directors on September 9, 1969."

The revised rules on Research Involving Human Beings, incidentally, were adopted by the faculty, June 9, 1969, state:

"All research whether supported by the Public Health Service or by any other source must follow the regulations set forth in the Public Health

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Service Document dated May 1, 1969 and entitle full protection of the individual as a research subject."

One..

In his letter of resignation, Denton A. Cooley, M.D., 1200 Moursund Avenue, Texas Medical Center, Houston, Texas 77025, 2 September 1969 addressed to Dr. Michael E. DeBakey, Office of the President, Baylor College of Medicine, Texas Medical Center, Houston, Texas, 77025:

Dear Dr. DeBakey:

The directive from the Board of Trustees requiring that all members of the faculty must agree to accept the action of the Committee on Human Experimentation at Baylor before preceding with clinical investigation places some members of the clinical faculty in an untenable position. For those whose research is neither funded by the College of Medicine or by federal grants this responsibility should reside solely with the research committee of the hospital in which the investigation will be done. The refusal of the committee at Baylor to accept or even consider the protocol for continuation of research with the orthotopic cardiac prosthesis after acceptance by the research committee of St. Luke's Episcopal Hospital and the Texas Heart Institute serves as an example of the obstacles which in my opinion will

prevent optimum patient care and furtherance of clinical research. Unless this requirement set forth by the Board of Trustees is withdrawn as applied to the clinical faculty, I can not in good conscience comply with the directive. Therefore, I must decline my appointment from your office as clinical professor of surgery for the academic year 1969-1970. Be assured that this decision is made after careful consideration without malice, but with sincere regrets.

Regardless of the above decision, be assured that whenever called upon to assist in the teaching activities of the College of Medicine, I shall be at your disposal.

Yours truly,

Denton A. Cooley, M.D.

Copies to: Mr. L.F. McCollum
Mr. J. Barry York
Mr. Robert R. Herring
Mr. Leopold L. Meyer
Dr. F. Brantley Scott
Dr. William D. Seybold

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DeBakey in reply is dated September 11, 1969:

Dear Dr. Cooley:

I have your letter of resignation as clinical professor of surgery dated September 2, 1969. It was upon a recommendation of your peers, the Executive Faculty Committee of Baylor, that the Board of Trustees adopted the guidelines on human experimentation to which you object. Of our one thousand three-hundred and fifty faculty members, both full-time and clinical who were required to sign this statement indicating their willingness to abide by the guidelines, you alone refused.

Dr. DeBakey goes on to explain to Cooley point by point that it is difficult to understand the logic of his statements in his letter pointing out that he can not condone dual standards--one for full-time faculty and another more relaxed for clinical faculty. That the school can not abdicate its responsibility in meeting the highest human research guidelines.

"Baylor must fulfill its own obligations if it is to preserve its honorable status. In the eyes of the scientific community and the world it is, in fact, held accountable for the activities and conduct of its faculty, as illustrated by recent events."

I'll ask DeBakey to copy this one for me.

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March 24, 1969--Los Angeles Times quotes Cooley as saying that the development of an artificial heart might not be as difficult as previously believed. There are no direct quotes in this story, but it seems to be some kind of general speech he made to the American College of Cardiology at the Century Plaza Hotel in Los Angeles based on the notion that an artificial heart can be much simpler than a real human heart. It does not have to be that complex.

The Long Island Press on April 5, 1969 reporting on the Karp operation says, rather quotes Dr. Cooley last August 3rd (that August 3rd, 1968, I suppose) at a seminar in Long Beach, California:

"The mechanical heart borders on science fiction and is wishful thinking." He told surgeons there, "A mechanical heart could never be more than a temporary substitute for cardiac transplant surgery"and said it would be three to five years before the artificial heart could be developed.

The same story quotes Dr. Liotta as saying the transplant, his first work, "a dream."

For what it's worth, the transplant was the one hundred and twenty-fourth in the short history of such operations. It would be the first artificial one. At that point forty-two heart transplant patients were alive.

Haskell Karp, forty-seven of Skokie, Illinois, who was employed as a printing estimator by the Creddson Printing Company. This is the story with a brief note that as Cooley was having his press conference two hours after the operation, someone came in with the information that Karp had responded to commence to raise and lower his hands and open and close his eyes.

Mariam Kass, Post reporter notes: "The news came--as he was talking to newsmen in a press conference and his eyes moistened. He said that this development was a sign that the artificial heart was performing properly. 'If this man wakes up, we've really passed a milestone,' Dr. Cooley said."

"Karp's wife Shirley and his older son Michael, twenty-two, are in Houston with him. Two other sons remain in Illinois, Joel, nineteen, and Martin, eleven. Shortly before nine p.m. the wife and son peered through the plate glass window at Karp for about fifteen minutes.

The original intention was to do a wedge-shaped procedure on the left ventricle, but the left ventricle was "ballooned-out with thin and weakened walls" according to a St. Luke's Hospital spokesman.

Dr. Cooley said he had discussed the possibility of an artificial heart implant with Karp and had received permission to go ahead if the

wedge procedure could not be used successfully. It was Cooley's seventh operation of the day. He explained, "I always save the hardest ones for last." It took him one hour to sew it in because he said the plastic was stiff. It normally takes half an hour to sew a whole heart in. At that point Cooley had performed eighteen human heart transplants according to the New York Post.

And he's quoted in the New York Post as saying, "The device is built in a way that it could work indefinitely."

A hospital administrator reported at 5:30 a.m. today, the day after the operation, said that Karp was "awake and alert and his condition remains stable and satisfactory as he awaits the availability of a suitable human heart donor."

The story says, "A working model of the artificial heart was developed in 1959 by Dr. Domingo Liotta of Argentina. Liotta, a professor at Baylor College of Medicine in Houston, assisted Cooley in the operation. Liotta and Cooley developed the artificial heart during the past four months. Liotta had used various models of the device over the past ten years on experimental animals including calves and dogs."

During the night, Mrs. Karp--Shirley Karp, an attractive dark-haired

woman, shown in a picture with her son Mike, a dark-haired boy, both obviously distraught and grieving, addressed a note, "Someone somewhere please hear my plea. A plea for a heart for my husband. I see him lying there breathing and knowing that within his chest is a man-made implement where there should be a God-given heart. How long he can survive, one can only guess...The Lord giveth and the Lord taketh, but the Lord also gave us gifted men such as Dr. Denton Cooley and Dr. Domingo Liotta who are instrumental in prolonging life..."

A Chicago Tribune story, April 5th, on this same thing:

"The artificial heart differs from that developed by Dr. Michael DeBakey of Houston in that DeBakey's device was used only to bypass the heart's left ventricle, the main pump of the heart. It was designed to give damaged hearts a rest so they could heal themselves."

And this same Chicago Tribune story quotes Cooley,

"If the artificial heart proves to be a success, it will permit us to retain life until a donor becomes available. The thing is built in a way that it can work indefinitely, but we must assume in the initial trial that it is a temporizing measure."

Same story reviewing the history says,

"The first experiment with the artificial heart was made in 1966 when DeBakey used his left-ventricular bypass on Marcel L. DeRauder, sixty-five of Westville. DeRauder died five days later. DeBakey of Houston's Methodist Hospital has performed ten human to human heart transplants. The longest surviving patient to have used DeBakey's left-ventricular bypass is Mrs. Esperanza Del Vallevasquez, thirty-seven of Mexico City, beauty operator. She underwent surgery August 8, 1966. There have been 122 human heart transplants on 120 patients. Forty patients survive."

Quotes Cooley, "The only thing we're worried about is irritation which could lead to infection," he said.

The same story says:

"When Karp entered the operating room in Houston yesterday, the doctors had told him that he had a 70 percent chance of living."

There are pictures showing Cooley and Liotta at their press conference afterward wearing white hospital coats still in their surgical clothes. Liotta-- dark hair, thin, very thin high brow, widow's peak, very dark thick eyebrows, long straight nose, fat lips, rather large ears. Chubby.

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A Miriam Kass story in the Houston Post April 5, 1969, under that picture says,

"The artificial heart was placed in the chest of a patient at St. Luke's Hospital Friday night as a modification of a working model developed ten years ago. Dr. Liotta developed the heart in 1959. He is a native of Argentina. He and Dr. Denton Cooley further developed the heart within the last four months. The control console was similar to many others that are commercially available. It was manufactured by engineers from Texas Medical Instruments. For the past ten years Dr. Liotta has been perfecting a device for total replacement of the heart. He used it on a.. He's used various models that arise on some experimental animals including calves and dogs. His first paper on the device was published in 1961. He is an assistant professor at Baylor. Funds for the development of this artificial heart came from the private foundations and research activities for the study were aided by grants from the heart association of Alice, Huntsville and Weimer, Texas. Dr. Cooley said calves have survived for several days with the device. Dr. Cooley said he has six of the artificial hearts available now, however it will only be possible to use one of them at a time because there is only one of the consoles available to power the devices. Dr. Cooley said they have used a new kind of valve that he thinks is better than the one used earlier for the artificial heart chamber

developed by Dr. Michael DeBakey. That chamber was actually a left-ventricular bypass that took blood from one storage chamber and completely bypassed the left ventricle. The heart valve used is called the "wada-cutter" hingeless heart valve. Cooley said he had been using the new valves in patients about--for about three months."

News story by Arthur J. Snyder dateline Houston in the Staton Island Advance says:

"Research on the artificial heart began in almost less than ten years ago. There are now some thirty prototypes developed, several of which have undergone trials in animals, such as calves and dogs. Survival after the artificial heart's been implanted in animals has not exceeded thirty hours. The operation at Baylor University in Houston was the first for a human being. It came as a surprise because the National Heart Institute which is financing most of the research throughout the country said it was holding in obedience an all-out program in the artificial heart because of some major problems."

The Chicago American reports that Karp looked up at his wife the day after the operation and murmured that his chest was sore.

Henry Reinhart, a hospital spokesman, said, "The only thing we know about the machine is through testing on animals. It worked for forty-seven hours on a calf before we removed it."

The same Chicago American story reports that Karp's wife watched part of the surgery from a gallery seat fifteen feet away, then tried to sleep late last night.

In Karp's case a heart donor with O positive blood is being sought. A donor was found last night after the artificial heart had been implanted in Karp and plans were quickly made to carry out the transplant. The body of a thirty-one year old woman who died in stillbirth in Cleveland, Texas, fifty miles away was rushed towards Houston in an ambulance while artificial means were used to keep the heart pumping. However, the woman's heart ceased to function when the ambulance was almost within sight of St. Luke's.

Cooley's record at that point was three survivals out of either eighteen or nineteen--the number seems to differ in these stories.

Liotta seems to have a down-turned mouth in all these pictures and very fleshy face. Heavy stubby fingers. Fat hands.

Dr. Liotta is quoted in the Philadelphia Daily News after the operation as saying the thing:

"It worked like 'a dream.' It is so much easier on a human."

The Los Angeles Times on April 5th says,

"The artificial heart had been completed for weeks, designed and built by an Argentine doctor, but the electrical pumping device was not made into

the artificial heart until last Tuesday. "

At the same seminar where Cooley made his statement about a mechanical heart bordering on science fiction, a Dr. Donald C. Harrison, Chief of the Cardiology Division, at Standford University Hospital in California said a secret government report "says the manufacturing, insertion, and servicing of artificial hearts will be the second largest industry in America in twenty years, second only to the auto industry. "

"Personally, I think the report is a little optimistic," Dr. Harrison said.

A New York Times story on the Karp operation backgrounding Cooley says:

"The forty-eight year old surgeon was born in Houston. He was the son of a dentist who persuaded him to take pre-medical courses at the University of Texas. He took his medical degree at Johns-Hopkins and interned there. Dr. Cooley studied with Lord Russell Brock, the heart surgeon at Brompton Hospital in London. He became a professor at Baylor in 1951. In 1967 in Vienna he was awarded the Leriche Prize by the International Surgical Society. Dr. Cooley's team had not performed any heart transplants until last November through the beginning of last month, because of a lack of donors.

The irony in this is that prior to the operation there had been some or at least DeBakey and Cooley's views publicly were defined as DeBakey favored artificial heart and Cooley favored human transplant. Noting last year Cooley described the artificial heart implant as "impractical, wishful thinking. It borders on science fiction."

Last September, quoting now the Houston Chronicle:

"Last September"--the Houston Chronicle, April 6, 1969 --"Last September Cooley said he would attempt to build his own artificial heart. His stated reason, however, was not a shift in his thinking, but merely the chronic shortage of heart donors. Cooley was assisted in the operation by Dr. Liotta, Dr. Grady L. Hallman, and Dr. Robert D. Bloodwell. Hallman and Bloodwell are regular members of the Cooley transplant team.

This is the Houston--no the Boston Herald Traveler, April 6:

"Dr. Domingo Liotta, forty-four, a native of Cordoba, Argentina who designed the artificial heart said fifty-seven different materials were tested before deciding on the right lining."

All over the world people said this was a fantastic thing. Dr. Seiji Kimoto, one of Japan's top surgeons, was surprised by "the unexpected earliness of the attainment."

Dr. Philip Blayburg, the longest living heart transplant patient at that time, said, "A fantastic step forward."

Cooley in a Houston Post story by Henry Holcolm, Post reporter,

"Dr. Denton Cooley said Saturday," (This is 4-6-69.) "The artificial heart implanted here Friday was not ready for use in humans, but that the historic operation was a 'act of desperation' to save a patient's life. 'This man was ostensibly dead yesterday. His only chance to live another hour was to have this device attached. If this is cause for censure or for criticism then I lay myself at the mercy of the court. I've done desperate things before on behalf of my patients and I have never regretted it.'"

"It is in itself miraculous that he has lived for twenty-four hours," Dr. Cooley said. "It is a breakthrough that we think is an important scientific development."

Dr. Cooley described Dr. Liotta as his "inspiration and associate." in the operation Friday. It was Liotta who designed the basic heart, but Dr. Cooley who led in the drastic breakthroughs of the last four months that made the operation Friday possible. Dr. Liotta credited Cooley with resolving difficulties in the design of the valve system and the area that is sewn to the human body. The mechanics of the heart given Karp were tested in about six calves.

Quote Cooley, "I would not have thought of doing it as an elective operation...I don't think it's fair to do something that has such an unknown quantity unless there's an emergency."

Dr. Cooley said use of the heart is not yet sanctioned by the Human Experimentation Committee at the Baylor College of Medicine where its development has advanced in recent years. Just before that--He said he consulted with no one prior to the operation.

"Even if Mr. Karp goes only one more day, I think we have demonstrated that there is validity to this concept. We are most encouraged by the results so far." That's from the same Henry Holcolm story in the Post. Houston Post.

A New York Times story notes:

"Two ambulance planes stood ready at the Houston airport to fly to any section of the country and pick up a donor."

St. Luke's Hospital said they were getting calls from all over the country from people who wanted to sacrifice themselves and become donors.

"Mr. Karp's physical condition improved today and he was able to prop himself up in bed and visit with his wife and son, Mike, twenty-two. 'I'm a lousy golfer, but I'd like to try again,' Mr. Karp was quoted as having said."

April 9, 1969--"Heart Patient Karp Dies--U. S. Agency Asks Report"--Houston Chronicle.

He received the heart of Mrs. Barbara Ewan, forty of Lawrence, Massachusetts, and died thirty hours later.

"Karp had lived sixty-five hours previously with an artificial heart

never before used in a human. "

Quotes Cooley as saying, "Mr. Karp himself was not in favor of a heart transplantation, but he realized he was at the end of his string."

Karp apparently did well on the device, although Dr. Cooley reported his patient suffered minor liver and kidney damage. Both Dr. Cooper and Dr. Frank Hastings of the National Heart Institute noticed--had noted that lung problems frequently accompany the experimental use of artificial hearts in animals. Cooper--that lung and kidney ailments are complications of artificial circulation of blood.

Dr. Liotta termed his heart a success. "It looked really wonderful," he said after it was removed from Karp. "It had a real fine lining. I believe he could have lived six months with it."

Philadelphia News : "Furor Erupts over Use of Mechanical Heart As Patient Dies"--April 9, 1969.

Says: "The man-made device is coming under attack from the National Heart Institute and Dr. Denton A. Cooley's superiors in Houston."

The New York Daily News in a copyrighted story today said medical authorities in Houston were investigating charges Dr. Cooley violated governmental guidelines on human experimentation when he inserted the artificial heart in Karp's chest.

This story in the Philadelphia Daily News says:

"The artificial heart implanted in Karp was never presented to such a committee (that is the Human Experimentation Committee) and Dr. Liotta said Dr. DeBakey was not even aware the device existed until it was placed into Karp."

A whole flood of stories on April 9th: "Authorities Question Use of Artificial Heart in Texas," etc.

"Dr. Frank Hastings of the National Heart Institute in Bethesda, Maryland, said yesterday, "Any medical innovation such as an artificial heart developed in whole or in part by Institute funds must go through rigorous tests and evaluations by persons other than the developer before it can be used. The Institute is very strict on this edict," Hastings said, "because there appears to be a tendency for doctors to use these innovations immediately after development!" "The aim of the Institute," Hastings said, "was to safeguard the patient."

Dr. Liotta said: "Dr. Hastings is a good friend of mine," said Liotta moments after learning of Karp's death. "But for the last five years, he has been out of any clinical work and out of contact with the patients."

Dr. Denton Cooley said that he was unaware that his colleague, Dr. Michael DeBakey, President of Baylor College of Medicine, had asked for

an investigation of his implantation of an artificial heart in forty-seven year old Haskell Karp of Skokie, Illinois.

A Los Angeles Times story in the interim. This is April 6th--some background on Liotta. Says "Liotta began building small artificial hearts and implanting them in dogs before he left Argentina in 1960. After joining the research staff in Houston's Baylor College of Medicine, he played a major role in the development of an artificial heart pump, a left-ventricular bypass designed to permit the heart's main pumping chamber to rest and repair itself. Dr. Michael E. DeBakey, another internationally known heart transplant surgeon, first made use of the bypass in 1966. Liotta said modifications made in recent months to a totally mechanical heart involved primarily the interlining. During these four months preceding the operation on Karp, the Cooley Foundation gave Liotta at least 50,000 dollars for his research, says one story.--Noting that Cooley's...or one story about the controversy.

A story about the controversy in the New York Post:

"DeBakey was not available for comment, but other medical sources at Baylor said the phrase 'outright piracy' was being used by his partisans in the incident which has raised a storm of controversy at the Baylor Medical Center. The contention is that Cooley simply appropriated the newest version of the artificial pump on which DeBakey had been working for more than a

decade. Did so without his superior's knowledge or permission. One claim from a source close to Cooley that the implant was decided upon when Karp's heart defect could not be mended in non-transplant surgery. It was contradicted by a DeBakey partisan who pointed out that workers on the experimental plastic and fabric pump had to be alerted a day in advance so that the device could be sterilized and available for use with the special power source and monitoring equipment it requires. Cooley has done more transplants than any other surgeon--nineteen, including one feudal effort to save a patient's life with a sheep heart. Three of his patients survive. DeBakey has done ten and also has three survivors.

Cooley is quoted during the controversy as saying,

"I "(and this is on April 10th)--"I don't have to clear my operations through them. (the research committee) " "The operations I do are designed to save a person's life. This was the purpose of my effort with Mr. Karp. He would have been dead Friday afternoon if I hadn't operated. It was a desperate attempt to save a life. "

The Associated Press quoted Dr. Liotta as saying, "This particular heart was developed through Dr. Cooley's Institute (The Texas Heart Institute). We have used federal funds through the years to gain experience and knowledge but this heart was not financed by the government. "

On April 11th, Cooley said that it was news to him that DeBakey had asked for an investigation. Asked if he would do an artificial implant again, Cooley replied emphatically, "Yes, I would under similar circumstances."

"I'm ready for any investigation, of course."

"The funds were from private sources which were made available to me," Cooley said. He also said the pump was a "separate enterprise" from artificial heart research at the Baylor College of Medicine which has a federal grant."

Cooley said an autopsy on Karp showed "no evidence that the artificial heart effected his system in any way. The human heart was not rejected. The cause of death was pneumonia which happened twenty-four hours after the transplant."

From that same news conference, Cooley said, "I really don't believe the seriousness of the investigation is of the magnitude that the public has been led to believe. I believe it is routine."

"I've done more heart surgery than anyone else in the world. I believe I am qualified on what is right and proper to do for my patients. The decisions are made by me with the permission of the patients. I don't see how I violated any government regulations. I'm ready for any investigation

of course. This is not the time for a witch hunt, but the time to proceed with the knowledge we have gained," Dr. Cooley said.

In a rambling press conference and a lecture to doctors attending the Annual Meeting of the Medical and Surgical Faculty of Maryland, Dr. Cooley defended his artificial heart implant and said he would do the same thing again.

Washington Post , April 11th, story by Stewart Auerbach:

Cooley said DeBakey and Liotta were working on a bypass of the left ventricle, not a total replacement for the heart. "This was not under study in the laboratory until I sought Dr. Liotta's advice," said Dr. Cooley. Dr. Cooley insisted that his experimental data through the use of nine calves justified the emergency implant last Friday night. Discussing the charge that he pirated Dr. DeBakey's design of an artificial heart, Dr. Cooley declared that he and Dr. Liotta started working on their heart four months ago in the Baylor surgical lab. "I have access to that lab which I have supported" with funds from the Texas Heart Institute. Dr. Cooley said, "I don't feel I should be denied access to the facility," which is also used by Dr. DeBakey.

The weekly paper, I guess, Medical Tribune published New York, April 21, 1969 quotes in an exclusive interview Dr. Robert D. Bloodwell, assistant professor of surgery at Baylor and a member of Dr. Cooley's team,

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quote:

"The artificial heart that we employed had features that were specifically designed in the light of Dr. Cooley's experience with human heart transplantation. It had cuffs like the opened atria in the biological homograft that were sutured on to the patient's residual atria. Although the device is essentially two-chambered, it thus functioned as a four-chambered structure according to Dr. Cooley's concept. We also for the first time employed hingeless valves designed by Dr. Juro Wada of Japan. The pump was made of a reticular Dacron material that has been shown to be anti-thrombogenic. We used no anti-coagulants and in fact, when the device was removed, there was no evidence of thrombi on any of its surfaces."

Newsweek's story notes such "entrepreneurship" as attracting a researcher away from a rival only feeds the growing suspicion that heart surgery's modern pioneers are going too far too fast.

By April 25th, Cooley is raising patriotic issues saying he was anxious the first implantation be done in the U.S. Noted "with some distress" that Christian Barnard did the first human heart transplant in South Africa. He said he kept his development a secret for fear he would be pressured into halting the project.

He was speaking in New York where he was to lecture at the Hospital for Joint Diseases. He said,

"Who would deny a dying man a chance to live longer."

Dr. C. William Hall speaking in San Antonio in a speech in which he was calling for more artificial heart research money said little was learned from the sixty-three hours that an artificial heart functioned in Karp's chest. "It wasn't in long enough to learn anything," he said.

"When we talk about tissue interfacing (synthetic linings and mechanical organs) we're talking about months and years, not a matter of hours."

One prominent cardiologist is quoted by the Los Angeles Times in a kind of round up heart story as saying,

"Let's be practical. Cooley was in a situation where a man was going to die. Does he have the right to put in the artificial device to try to save him, but without asking the advice of the committee? You're damn right he does. But if he planned it ahead of time and didn't ask for advice, then he's a bad boy."

In a story by Will McNutt in the Omaha World Herald about Domingo Liotta: Out of the shadows Domingo Liotta forty-four, a sad-eyed surgeon from Argentina overshadowed by Cooley and DeBakey. Wants to carry on

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his work. Observing him in action you wonder if Dr. Liotta is not himself a candidate for a heart attack. Earnest, seldom smiling, restless, never enough time for all the things he wants to do. Seated in his office at Baylor Medical School in Houston, Dr. Liotta, his dark eyes reflecting both excitement and a grueling schedule, reviewed his part in the development of the mechanical heart. "Dr. Cooley and I set out four months ago to build an artificial heart and establish the feasibility of using it in a heart transplant operation," he spoke in a rich, Spanish accent. "I spent about 90 percent of my time at the hospital and the medical school," he said. Such hours impose a serious burden on the father of six children, three boys and three girls whose ages range from ten months to nine years. "Fortunately my wife understands. She is happy because both our ambitions are to save lives." The present artificial heart looks crude, but it is highly refined compared with the first hard plastic model Dr. Liotta developed at Argentina's University of Cordoba School of Medicine in 1959. He takes the original model from his desk drawer, fingers it lovingly, recalls that it kept a dog alive for thirteen hours although the animal never regained consciousness. "It was a big achievement at that time, although we knew nothing of the blood clotting problem then," he said. "This has been a fantastic experience. Just imagine how much we have learned from this single case. The practical knowledge and scientific data."

Cooley quoted in a U.P.I. story, Houston, May 18, 1969 said he will continue to use the artificial heart in transplant operations when he thinks it is necessary. "I still consider it my heart. I will use it again if the occasion arises. I have a heart available to use."

Cooley said he planned to hire Liotta to work at the Texas Heart Institute and would use Institute funds, not federal funds to pay his salary.

"Let the records show we tried and also let the doubting ones know that we will try again," Cooley said.

Liotta said he would agree to sign the new Baylor pledge on human experimentation.

A U.P.I. story May 19, "Domingo Liotto fired two days ago by the Baylor College of Medicine because of an artificial heart hewas used without permission. Will be put in charge of Dr. Denton A. Cooley's Manmade Heart Research Program."

Clips note that the Baylor College of Medicine declined to turn over its full report of the investigation on grounds that many of the witnesses requested their testimony be kept confidential.

Medical World News , June 13, 1969, notes that two new investigations one by the American College of Surgeons and the other by a House Sub-Committee on Inter-Governmental Relations chaired by Representative L. H. Fountain, Democrat of North Carolina are quietly proceeding. Both, according to

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Medical World News "are concerned over the medical ethics of the procedure."

Dr. John Paul North of the A. C. S., American College of Surgeons, said, "We are endeavoring to ascertain whether Dr. Cooley's conduct in this regard has been consistant with his fellowship pledge. He is a fellow of the A. C. S., and for that reason we are deeply concerned. If he has not as alleged both in the press and privately adhered to ethical standards, the Board of Regents of the A. C. S. is obligated to take appropriate action."

William O'Bannon described in a story here as forty-four years old and in--that's April 25, 1966, is a mechanical engineer without a college degree. He left mechanical engineering studies at the University of Houston because he had a job offer that would pay off his debts. He is described as one of the best men available for that kind of work. He joined the Rice team...

This is a story about all of the Rice people, apparently, involved in the artificial heart program.

END SIDE B of TAPE # 11